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EXAMINER

COUNTS, GARY W

ART UNIT

PAPER NUMBER

1641

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17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/582,741

Applicant(s)

MENDEL-HARTVIG ET AL.

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6 and 11-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6 and 11-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of the claims***

The Request for Continued Examination and the amendment filed on June 30, 2003 is acknowledged and has been entered.

### ***Claim Objections***

1. Claim 1, part (iii) is objected to because of the following informalities: the recitation "obtaining" should be --determining--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-4, 6 and 11-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, part (ii) the recitation "sample value" is vague and indefinite. It is unclear if the recitation contained within the parenthesis ( ) is actually part of the claim or not.

Claim 1, lines 16 and 17 is vague and indefinite because it is unclear why or how the calibrator is released.

Claim 1, line 19 the recitation "capable of" is vague and indefinite. The recitation is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Claim 12, line 2, the recitation "exhibit" is vague and indefinite. Does the calibrator zone have a calibrator binder or not. It is recommended to change "exhibit" to --comprise--.

Claim 14 the recitation "having access to" is vague and indefinite. It is unclear what applicant intends. Is a standard curve being used or a second calibration zone?

Claim 14, part (b) the recitation "Positive Internal Calibrator = PIC) is vague and indefinite. It is unclear if the recitation contained within the parenthesis ( ) is actually part of the claim or not.

Claim 14, part (c) "adapting the measurement signal" is vague and indefinite. It is unclear how the measurement signal is adapted.

Claim 14, part (c) "the deviation of the measurement signal from the separate calibrator values" there is insufficient antecedent basis for this limitation.

Claim 20, line 6 the recitation "exhibits" is vague and indefinite. Does the device have the recited limitations or not? It is recommended to change "exhibits" to --comprises--.

Claim 23 the recitation "via" is vague and indefinite. It is unclear what the term encompasses.

Claim 23 the recitation "Capturer" is vague and indefinite. It is unclear what applicant is referring to. Is applicant referring to Reactant I or is applicant referring to the analyte which binds to Reactant I and then binds to Reactant\* or is applicant referring to something else?

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-3, 6, 11-18, 20-25 and 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rylatt et al (WO 97/09620) in view of Van Deusen et al (US 5,132,097).

Rylatt et al disclose a method and device for the quantitative determination of a target analyte in a test sample. Rylatt et al disclose a lateral flow permeable medium (matrix) comprising a calibration zone and a detection zone. Rylatt et al disclose the application zone for labeled calibration agent and labeled analyte agent (Reactant \*) is located upstream of the calibration zone. Rylatt et al disclose a test (detection) zone downstream of the calibration zone (Figures 2,5,8). Rylatt et al also disclose a non-diffusibly attached analyte receptor (Reactant I) in the detection zone. Rylatt et al disclose that the calibrator or calibrator agent can be immobilized in the calibration zone. Rylatt et al disclose that the comparison of the signals generated in the test (detection) zone and the calibration zone is used to determine the concentration of analyte in the sample. Rylatt et al disclose that the lateral flow medium can be read visually or can be read instrumentally (p. 27). Rylatt et al disclose that the target analyte can be an antibody (p. 5). Rylatt et al disclose the invention comprises a kit for

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use in the methods disclosed by Rylatt. Rylatt et al disclose that the calibration agent can be a calibration agent which has high affinity for the specific binding partner (p. 9).

Rylatt et al differ from the instant invention in failing to teach the calibrator and the analyte biospecifically bind to Reactant\* by equivalent binding sites.

Van Deusen et al disclose a test strip comprising a standard area (calibration zone) and test area (detection zone). Van Deusen et al disclose reactant B (calibrator) (col 4, Figures 1-3) immobilized to the calibration zone. Van Deusen et al disclose labeled reagent which binds to both the calibrator and the analyte (col 4, lines 34-54). Van Deusen et al disclose that the use of this labeled reagent provides for a standard area and a test area having both calibrator and analyte produced on the same test strip and provides for a method in which it is not necessary for the reactants to come to equilibrium, but instead allows for a time base to be established for the allowed reaction time for the formation of the complex in the test area to which the number of complexes and standard (calibrator) may be compared (col 4, lines 45-54).

It would have been obvious to one of ordinary skill in the art to incorporate calibration agents and labeled reagents as taught by Van Deusen et al into the method and device of Rylatt et al because Rylatt et al is generic with respect to the calibrator agent and labeled agent. Further, Van Deusen et al shows that the use of this labeled reagent provides for a standard area and a test area having both calibrator and analyte produced on the same test strip and provides for a method in which it is not necessary for the reactants to come to equilibrium, but instead allows for a time base to be established for the allowed reaction time for the formation of the complex in the test

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area to which the number of complexes and standard (calibrator) may be compared. It would also provide the advantage of reducing the number of reagents used for the determination of a target analyte.

6. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rylatt et al and Vandeusen et al in view of Self et al (US 4,446,231).

See above for teachings of Rylatt et al and Van Deusen et al.

Rylatt et al and Van Deusen et al differ from the instant invention in failing to teach the diagnosis of an autoimmune disease.

Self et al disclose that immunoassays are used for the detection and/or determination of autoimmune diseases. Self et al disclose shows that immunoassays have a wide application, in both clinical and non-clinical fields and that they are particularly useful in any circumstance where it is necessary to detect and/or determine small or very small amounts of substances.

It would have been obvious to one of ordinary skill in the art to use immunoassays as taught by Self et al for the diagnosis of autoimmune diseases because Self et al that immunoassays are used for the detection and/or determination of autoimmune diseases and that immunoassays have a wide application, in both clinical and non-clinical fields and that they are particularly useful in any circumstance where it is necessary to detect and/or determine small or very small amounts of substances.

7. Claims 4 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rylatt et al and Van Deusen et al in view of Weng et al (US 4,740,468).

See above for teachings of Rylatt et al and Van Deusen et al.

Rylatt et al and Van Deusen et al differ from the instant invention in failing to teach an immobilized reactant that is biospecific to a second reactant which in turn has biospecific affinity to the analyte.

Weng et al disclose the use of a specific binding partner that is biospecific to a second binding partner, which is in turn specific for the analyte (col 2, lines 47-53).

Weng et al disclose that is useful for determining the presence of an analyte in a sample suspected of containing the analyte (col 2, lines 39-41) and also allows for the determination of a plurality of analytes in a test solution (col 3, lines 20-27).

It would have been obvious to one of ordinary skill in the art to incorporate the use of an immobilized specific binding partner (reactant) as taught by Weng et al into the modified method and device of Rylatt et al because Weng et al shows that this specific binding partner allows for the determination of a plurality of analytes in a test solution

### ***Response to Arguments***

8. Applicant's arguments with respect to claims 1-4, 6 and 11-31 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's argument that the device and procedure described by Rylatt et al includes a test zone arranged between calibration zones 210 and 211 (Fig. 2) and that the detection zone or test zone is not downstream of the one or more calibration zones, but interspersed therein. Examiner agrees that the test zone is interspersed between two calibration zones. However, the claim recites one or more calibration zones, and



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one or more detection zones (test zones) downstream of said one or more calibration zones. Rylatt et al clearly disclose a calibration zone (Fig. 2 (210) and a detection zone (204) downstream of the calibration zone. Therefore, since the claims only require one calibration zone, Rylatt et al reads on the instantly recited claim.

**Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gary W. Counts  
Examiner  
Art Unit 1641  
September 15, 2003



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09/19/03